UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

DATE: April 26, 1999

MEMORANDUM

SUBJECT: Update of Incident Data on Chlorpyrifos for Domestic Animals

PC Code: 059101
DP Barcode: D255514
Case: 818975
Submission: S466596

FROM: Virginia A. Dobozy, V..M.D., M.P.H.
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THRU: Whang Phang, Ph.D., Branch Senior Scientist
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TO: Deborah Smegal
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Background

A review and analysis of the incident reports on domestic animals for Chlorpyrifos was conducted in 1995 (Memo dated January 23, 1995 from Virginia Dobozy to Bruce Kitchens). Incidents in dogs and cats were categorized as exposure by direct applications (flea and tick dips, sprays, collars, etc.) or by premise applications (household and lawn treatments). The analysis found that the majority of the incidents in domestic animals involved cats, although the chemical is registered only for use in flea collars for this species. Cats which were exposed to products registered only for use on dogs, mainly dips, experienced a high incidence of death (30%). There was also evidence of misuse of premise treatment products, including practices such as applying these products directly to animals and not removing pets from premises during applications.

Update to 1995 Memo

In 1996, the draft PR Notice mentioned in the 1995 review was finalized and published as PR Notice 96-6. Under this notice, labels for all products administered directly to animals were revised to assure adequate directions for use and warning information was provided.

In 1997, DowElanco announced the establishment of a ten-point program to further the safe use of Dursban insecticides (active ingredient, chlorpyrifos). Under this plan, the registrant withdrew its registrations for indoor broadcast flea control and direct application pet care products, except for flea collars, and committed to expedite implementation of PR Notice 96-6 on pet products. Since 1995, there has been an evolution in flea and tick control treatments, with three products containing new active ingredients now being the most widely used. One of these products is orally administered and as such is regulated by the Center for Veterinary Medicine, Food and Drug Administration. The other two are spot-on preparations and sprays registered by EPA. These three products are either by regulation (FDA) or company policy sold only through veterinarians. Spot-on preparations have also become popular for general distribution products (sold in pet stores, grocery stores, etc.) that contain older chemicals (e.g., permethrin).

Incident Reports Since 1995

The incident reports for domestic animals involving chlorpyrifos in the Incident Data System were tabulated for the years 1996 through 1998. Due to time constraints, a complete analysis of the data could not be conducted. However, general impressions are provided in this memo. One impression is that there has been a shift in the percentage of incidents resulting from exposure to products registered for direct use on animals as compared to the percentage of incidents resulting from premise exposure. The former has decreased and the latter increased. The number of incidents per year and the number attributed to pet products are presented below.

Year	Number of Incidents	Number of Incidents Attributed to Pet Products (%)
1996	130	10 (8%)
1997	123	8 (7%)
1998	63	8 (13%)

In the 1995 review, approximately 32% of the 277 incidents involved products registered for direct application to dogs and cats, approximately 61% involved exposure of dogs and cats through premise treatments, and approximately 8% involved other domestic animals. The reason for this perceived shift are unknown. The same data limitations as described in the 1995 Memo are also applicable now.

Another general impression is that deaths are still being reported, with more occurring in cats than other species. The exact number on an annual basis cannot be determined without a detailed analysis of the incident reports.

Conclusions/Recommendations

1. The cancellation of indoor broadcast flea control applications and products for direct application to dogs and cats should reduce the risk of serious adverse reactions and deaths in these animals. The time required to eliminate all chlorpyrifos products registered for direct use on animals from store shelves cannot be predicted. Therefore, it may be premature to review the IDS reports for evidence that these actions were effective.

2. Labels for premise applications should contain instructions to remove pets from the area during treatment and until the area is dry. This applies to both indoor and outdoor applications of chlorpyrifos.